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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,888	10/19/2004	Dirk Cremer	5942/83518	4210

22242 7590 06/22/2010

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,888	CREMER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12,15,16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,15,16 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/29/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges receipt request for extension of time, IDS, amendment and remarks 3/29/2010. Claims 1 and 21 are amended. Claims 1-3, 5-12, 15, 16 and 18-24 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 15, 16 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) for reasons of record and minor modification top address the amendment to claims 1 and 21.

5. Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; the composition meeting the limitations of claims 1-3, 5, 15, 16 and 20-23 in the sense that phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids meeting the percent limitation in claim 2; the DHA and EPA omega fatty acids meet the fractionated fat of claim 5. The composition of Kiliaan is administered to treat vascular disorders/dementia syndromes (page 1, lines 6-9) meeting claim 15. On page 6, lines 21-30, Kiliaan discloses that the composition of contains eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), arachidonic acid at a ratio of EPA +DHA to DHGLA +AA of 2.5 to 5.5%, or mixtures. EPA and DHA are fat and phospholipids are also fats. In Example 1, the amount of the fat is at (50 + 75 + 250)/830.3 = ~45% meeting the requirements of the limitation of 20-50% fat in claims 1 and 20-22. The phosphatidyl serine at 14.4% anticipates the requirement that the phosphatidyl serine be at a range of 10-40% in claims 1 and 20-22, 15-30% in claims 2, 16 and 23. The phosphatidyl choline at 15.6% anticipates the requirement that the phosphatidyl choline be at a range of 1-90% in claims 1 and 20-22, 2.0-20% in claims 3 and 23. The presence of fat (the omega fatty acids and the phospholipids) and vitamins (Example 1 and claims 10 and 11) meet the requirement for

the presence of broad fat and additives in claim 5. The capsule meets the limitation of solid matrix.

6. The composition of Kiliaan does not contain wax. But della Valle discloses composition comprising phosphatidyl serine, phosphatidylethanolamine or phosphatidylcholine and beeswax (abstract; column 2, lines 29-38; column 9, lines 54-63); the composition is used for the treatment of pathologies such as vascular complications from old age and dementia (column 5, lines 50-59).

7. Kiliaan uses the composition to treat vascular disorders including dementia. The composition of della Valle is also used to treat dementia. Therefore, taking the combined teachings of Kiliaan ands della Valle, one having ordinary skill in the art at the time the invention was made would have reasonably expected that a third composition derived from the combination of the composition of Kiliaan and della Valle would be effective in treating dementia. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

8. Applicant's arguments filed 3/29/2010 have been fully considered but they are not persuasive.

9. Applicant argues that Example 1 of Kiliaan is a liquid and that Kiliaan does not disclose a wax component; that the discussion in the declaration by Dirk Cremer and Elisabeth Markl supports the argument that the composition of Kiliaan in Example 1 is a liquid.

10. Response: The examiner agrees with the applicant that Kiliaan does not have wax in its composition and that is why the rejection was made under 35 USC 103. However, there is nothing in Kiliaan that says that the composition in example 1 is a liquid. Example 1 does not disclose that the capsule is filled with liquid formulation. According to the response of 9/29/2009, the declarations are opinion declarations and the rejection over Kiliaan in view of della Valle specifically noted that the Kiliaan composition does not contain wax. It is because of the absence of wax in Kiliaan that della Valle was used to show that compositions containing phosphatidyl serine have been known to be formulated with wax. Opinion declarations cannot overcome the Kiliaan composition that does not say that the composition is a liquid since the basis for applicant's conclusion is not supported by factual showing.

11. Applicant argues that Kiliaan or della Valle alone or in combination does not suggest or disclose how to stabilize matrix containing phosphatidyl serine and phosphatidyl choline, how to encapsulate solid matrix containing "these compounds," or that the stability of phosphatidyl serine and phosphatidyl choline can be significantly improved.

12. Response: the claims are not directed to how to stabilize phosphatidyl serine and phosphatidyl choline matrix, or how to encapsulate phosphatidyl serine and phosphatidyl choline or how to improve the stability of phosphatidyl serine and phosphatidyl choline. Rather the claims are directed to solid matrix that comprise phospholipid and a solid matrix that is encapsulated. The matrix of Kiliaan is encapsulated. Applicant cannot also import limitations

form the specification into the claims and thus applicant's reference to page 2 of the specification is an attempt to import limitations from the specification into the claims.

13. Applicant argues that claims 20 and 22 recite that the matrix is solid or paste like at room temperature and that the combination of Kiliaan and della Valle does not suggest that it is possible or desirable to prepare stable solid matrix containing phosphatidyl serine and phosphatidyl choline.

14. Response: Claim 20 states in relevant section "...wherein the bioactive component and the further matrix component are in amounts and ratios which are effective to (a) make the bioactive component containing matrix solid or paste-like at room temperature" so that it is clear that claim 20 does not say that the matrix is solid; rather the claim is stating that the bioactive component and the matrix components are combined in amounts and ratios so as to form a matrix and the language is more of how the to form a matrix by combining appropriate amounts of the matrix component and the bioactive component to form a solid or paste --- the claims do not also recite the amounts of the components that are required for the formation of the solid or paste. Claim 22 is similar to claim 20 as it relates to the matrix component being effective to make the bioactive component containing matrix solid or paste-like.

15. Therefore, Kiliaan in view of della Valle renders obvious the claims for reasons of record.

16. Claims 1-3, 5, 15, 16, 19 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) and further in view of Patel et al. (US 6,294,192).

17. Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) has been described to render claims 1-3, 15, 16 and 20-23 obvious.

18. The DHA and EPA listed in the composition of Example 1 of Kiliaan meet the compositional requirement of claim 19. The combined composition of Kiliaan and della Valle does not contain the polyol recited in claim 5. However, hydrophobic active agents have been known to be solubilized by surfactants. For example, the phospholipids, phosphatidyl choline and phosphatidyl serine are hydrophobic.

19. Patel uses mixtures of hydrophilic surfactant and hydrophobic surfactant to solubilize hydrophobic agents (abstract; columns 5 and 6) and also suggests that solubilizers such as alcohols and polyols, namely, ethanol, ethylene glycol, polyethylene glycol (column 25, lines 14-54) can also be included in the compositions as solubilizing agents. Therefore, taking the teaching of Kiliaan and Patel, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that including polyethylene glycol or in combination with any of the other solubilizers would solubilize the phosphatidyl serine and phosphatidyl choline for effective delivery.

Response to Arguments

20. Applicant's arguments filed 3/29/2010 have been fully considered but they are not persuasive.

21. Applicant argues that Patel does not cure the deficiencies of Kiliaan and della Valle because Patel's formulation is intended to form aqueous dispersion, which can be administered as a solid dispersion; that Patel does not disclose of suggest that it is possible or desirable to prepare

stable solid matrix that contains phosphatidyl serine and phosphatidyl choline and which can be encapsulated, and does not suggest ratios recited in the claims.

22. Response: The examiner disagrees with applicant that Patel does not cure the deficiencies of Kiliaan and della Valle. Pate is relied upon for teaching using polyol such as ethylene glycol and polyethylene glycol to solubilze hydrophobic agents and because phosphatidyl serine and phosphatidyl choline are hydrophobic, the artisan would reasonably expect that these polyols such as ethylene glycol and polyethylene glycol would effectively solubilize hydrophobic agents such as phosphatidyl serine and phosphatidyl choline. The claims are not directed to stabilize solid matrix of phosphatidyl serine and phosphatidyl choline and as such Patel does not have to teach stabilization phosphatidyl serine and phosphatidyl choline.

23. Claims 1, 6-12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) and further in view of Winston, Jr. et al. (US 5,342,626).

24. Kiliaan in view of della Valle has been described above to render claim 1 obvious. The combined composition does not have encapsulating material to have water required by claim 6.

25. But, Winston, Jr. discloses that gelatin polymers and non-gelatin materials can be used in encapsulation, that these polymers such as gellan gum, carrageenan and mannan gum re-melt under controlled conditions to form soft capsules that seal encapsulated contents (see the entire document with emphasis on the abstract, column 1, lines 7-12 and 62-68; column 2, lines 9-18). The %water in capsule after solvent removal and drying is at a predetermined amount of 3-4% (column 4, lines 59-65; column 7, lines 51-55). The gelatin free capsule shell of Winston, Jr.

further comprises plasticizers selected form sorbitol, glycerin, propylene glycol, corn syrup, sucrose, fructose and polyethylene glycol and mixtures (column 4, lines 42-47; claim 3). The carrageenans and sorbitol meet claims 8 and 9. The capsule of Winston, Jr. may also contain dyes (column 8, lines 12, 13) so that claim 10 is met. Winston, Jr. teaches that the water insoluble liquids are microencapsulated, that the encapsulation masks the taste of unpleasant tasting compositions and further protects oxidation of these compositions and allows for controlled release of these compositions (column 8, lines 14-19). Thus, with regards to claim 11, one having ordinary skill in the art would be motivated to use amounts of the coating or encapsulating material relative to the composition that would provide effective masking of the taste, provide the desired controlled release of the composition and be also effective in protecting the composition from oxidation so that the ratio of the coating to the bioactive agent would be obvious. The 3-4% moisture content of the capsule shell anticipates the water/moisture content of 1.0 to 10.0% of claim 7. Since Winstson, Jr. contemplates microencapsulation or microcapsules and because microcapsules would have diameters in the micrometer range, the microcapsule of Winston would be expected to fall within the diameter recited in claim 12. There is no demonstration that the recited diameter of the matrix provides unexpected results.

26. Therefore, taking the teaching of Kiliaan et al. (WO 0184961) and della Valle et al. (US 4,595,680) and Winston, Jr. et al. (US 5,342,626), one having ordinary skill in the art at the time the invention was made would reasonably expect that the presence of moisture in the capsule would effectively control the melting temperature and proper sealing of the capsules.

27. Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) and further in view of Winston, Jr. et al. (US 5,342,626) for reasons of record.

28. Kiliaan in view of della Valle has been described above to render claim 22 obvious. The combined composition does not have encapsulating material to have water required by claim 24.

29. But, Winston, Jr. discloses that gelatin polymers and non-gelatin materials can be used in encapsulation, that these polymers such as gellan gum, carrageenan and mannan gum re-melt under controlled conditions to form soft capsules that seal encapsulated contents (see the entire document with emphasis on the abstract, column 1, lines 7-12, 62-68; column 2, lines 9-18). The %water in capsule after solvent removal and drying is at a predetermined amount of 3-4% (column 4, lines 59-65; column 7, lines 51-55). The gelatin free capsule shell of Winston, Jr. further comprises plasticizers selected form sorbitol, glycerin, propylene glycol, corn syrup, sucrose, fructose and polyethylene glycol and mixtures (column 4, lines 42-47; claim 3). The carrageenans and sorbitol meet the components of claim 24. Winston, Jr. teaches that the water insoluble liquids are microencapsulated, that the encapsulation masks the taste unpleasant tasting compositions and further protects oxidation of these compositions and allows for controlled release of these compositions (column 8, lines 14-19).

30. Therefore, taking the teaching of Kiliaan et al. (WO 0184961) and della Valle et al. (US 4,595,680) and Winston, Jr. et al. (US 5,342,626), one having ordinary skill in the art at the time the invention was made would reasonably expect that the presence of moisture in eth capsule would effectively control the melting temperature and proper sealing of the capsules.

Response to Arguments

31. Applicant's arguments filed 3/29/2010 have been fully considered but they are not persuasive.

32. Applicant argues Winston Jr. does not cure the deficiencies of Kiliaan and della Valle because Winston Jr. does not suggest or disclose that it is possible or desirable to prepare stable solid matrix comprising phosphatidyl serine and phosphatidyl choline and does not suggest the components and ratios recited in the claims.

33. The examiner disagrees because Winston Jr. was relied upon for teaching the presence of moisture within capsules and the water present in the capsule effectively controls the melting temperature and proper sealing of the capsules. Winston Jr. was not relied to show preparation of stable solid matrix containing phosphatidyl serine and phosphatidyl choline; the claims are not directed to process of preparing stable solid matrix containing phosphatidyl serine and phosphatidyl choline.

34. No claim is allowed.

35. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618